We claim:

1. A solid oral controlled-release oral dosage form, the dosage form comprising an analgesically effective amount of hydrocodone or a pharmaceutically acceptable salt thereof, and controlled release material to render said dosage form suitable for twice-a-day administration to a human patient, said dosage form after a first administration to a human patient, providing a C_{12}/C_{max} ratio of 0.55 to 0.85, said dosage form providing a therapeutic effect for at least about 12 hours.

2. The dosage form of claim 1 wherein said hydrocodone is dispersed in a matrix comprising said controlled release material.

3. The dosage form of claim 2 wherein said matrix is in multiparticulate form.

4. The dosage form of claim 3 wherein said multiparticulates are compressed into a tablet.

5. The dosage form of claim 3 wherein said multiparticulates are disposed in a pharmaceutically acceptable capsule.

6. The dosage form of claim 1 which provides a C_{12}/C_{max} ratio of 0.65 to 0.75.

7. The dosage form of claim 1 which provides an in-vitro release of from 18% to about 42.5% by weight of the hydrocodone or salt thereof from the dosage form at one hour when measured by the USP Basket Method at 100 rpm in 700 ml of Simulated Gastric Fluid (SGF) for 55 minutes at 37°C and thereafter switching to 900 ml of Simulated Intestinal Fluid (SIF) at 37°C.

8. The dosage form of claim 6 which provides an in-vitro release of from 18% to about 42.5% by weight of the hydrocodone or salt thereof from the dosage form at one hour when measured by the USP Basket Method at 100 rpm in 700 ml of Simulated Gastric Fluid (SGF) for 55 minutes at 37°C and thereafter switching to 900 ml of Simulated Intestinal Fluid (SIF) at 37°C.

9. The dosage form of claim 1, which provides a dissolution rate in-vitro of the hydrocodone dosage form when measured by the USP Basket method at 100rpm in 900 ml aqueous buffer at a pH of 1.2 at 37°C from about 25 to about 65% by weight hydrocodone or salt thereof released after 2 hours, from about 45 to about 85% by weight hydrocodone or salt thereof released after 4 hours, and greater than about 60% by weight hydrocodone or salt thereof released after 8 hours.

10. The dosage form of claim 1, which provides a dissolution rate in-vitro of the hydrocodone dosage form when measured by the USP Basket method at 100rpm in 900 ml aqueous buffer at a pH of 7.5 at 37°C from about 25 to about 65% by weight hydrocodone or salt thereof released after 2 hours, from about 45 to about 85% by weight hydrocodone or salt thereof released after 4 hours, and greater than about 60% by weight hydrocodone or salt thereof released after 8 hours.

11. The dosage form of claim 1, which provides a T_{max} of hydrocodone in said patient at from about 2 to about 8 hours after oral administration of the dosage form.

12. The dosage form of claim 1, which provides a T_{max} of hydrocodone in said patient at from about 3 to about 7 hours after oral administration of the dosage form.

13. The dosage form of claim 1, which provides a T_{max} of hydrocodone in said patient at from about 4 to about 6 hours after oral administration of the dosage form.

14. The dosage form of claim 1, provides a plasma concentration of hydrocodone of at least 8 ng/ml at from about 2 to about 8 hours after administration and provides a plasma plasma concentration of hydrocodone of at least 6 ng/ml at about 12 hours after administration, based on oral administration of a dosage form containing 15 mg hydrocodone bitartrate.

15. The dosage form of claim 14, which provides a plasma plasma concentration of hydrocodone of at least 8 ng/ml at from about 3 to about 7 hours after administration.

16. The dosage form of claim 1 which provides a C_{max} of hydrocodone which is less than 50% of the C_{max} of an equivalent dose of an immediate release hydrocodone reference formulation.

17. The dosage form of claim 1 which provides a C_{max} of hydrocodone which is less than 40% of the C_{max} of an equivalent dose of an immediate release hydrocodone reference formulation.

18. The dosage form of claim 1 wherein the dosage form provides a time to 80% mean C_{max} which is about 90% to about 110% of the time to 80% mean C_{max} of an equivalent dose of an immediate release hydrocodone reference formulation.

19. The dosage form of claim 1 which provides a time to 80% mean Cmax of hydrocodone from about .5 to about 1.5 hours.

20. The dosage form of claim 1 wherein the dosage form provides a time to 90% mean C_{max} which is about 150% to about 250% of the time to 90% Cmax of an equivalent dose of immediate release hydrocodone reference formulation.

21. The dosage form of claim 1 which provides a time to 90% mean C_{max} of hydrocodone from of about 1.5 to about 2.5 hours.

22. The dosage form of claim 1 which provides a time to 90% mean C_{max} of hydrocodone from about 1.8 to about 2.2 hours.

23. The dosage form of claim 1 which maintains a plasma concentration within 80% of C_{max} for about 1 to about 9 hours during the 12 hour dosing interval.

24. The dosage form of claim 1 which maintains a plasma concentration within 80% of C_{max} for about 4 to about 8 hours during the 12 hour dosing interval.

25. The dosage form of claim 1 which maintains a plasma concentration within 90% of C_{max} for about 1 to about 6.5 hours during the 12 hour dosing interval.

26. The dosage form of claim 1 which maintains a plasma concentration within 90% of C_{max} for about 2 to about 5 hours during the 12 hour dosing interval.

27. The dosage form of claim 1 which provides a T_{max} at a time point 3 to 4 times later than the T_{max} provided by an equivalent dose of an immediate release hydrocodone reference formulation.

28. The dosage form of claim 1, provides a mean in-vivo absorption rate from administration to T_{max} from about 1.5 mg/hour to about 5 mg/hour and provides a mean rate of absorption from T_{max} to the end of the dosing interval which is less than about 0.5 mg/hour based on oral administration of a dosage form containing 15 mg hydrocodone bitartrate.

29. The dosage form of claim 28 which provides a mean in-vivo absorption rate from administration to T_{max} from about 2 mg/hour to about 4 mg/hour.

30. The dosage form of claim 28 which provides a mean in-vivo absorption rate T_{max} to the end of the 12 hour dosing interval which is from about 0.08 mg/hour to about 0.4 mg/hour.

31. A solid oral controlled-release oral dosage form, the dosage form comprising an analgesically effective amount of hydrocodone or a pharmaceutically acceptable salt thereof, controlled release material to render said dosage form suitable for twice-a-day administration to a human patient, said dosage form after a first administration to a human patient, providing a rate of absorption during the time period from T_{max} to about 12 hours after oral administration of the dosage form which is from about 55% to about 85% of the rate of elimination during the same time period, said dosage form providing a therapeutic effect for at least about 12 hours.

32. A solid oral controlled-release oral dosage form comprising an analgesically effective amount of hydrocodone or a pharmaceutically acceptable salt thereof together with controlled release material to render said dosage form suitable for twice-a-day administration to a human patient, said dosage form after a first administration to a patient population, providing a T_{max} of hydrocodone in-vivo at from about 2 to about 8 hours, and providing a

C_{12}/C_{max} ratio of 0.55 to 0.85, said dosage form providing a therapeutic effect for at least about 12 hours.

33. A solid oral controlled-release oral dosage form comprising an analgesically effective amount of hydrocodone or a pharmaceutically acceptable salt thereof together controlled release material to render said dosage form suitable for twice-a-day administration to a human patient, said dosage form after a first administration providing a C_{max} of hydrocodone which is less than about 50% of the C_{max} of an equivalent dose of an immediate release hydrocodone reference formulation, said dosage form providing a therapeutic effect for at least 12 hours.

34. A solid oral controlled-release oral dosage form comprising an analgesically effective amount of hydrocodone or a pharmaceutically acceptable salt thereof and controlled release material to render said dosage form suitable for twice-a-day administration to a human patient, said dosage form after a first administration providing a time to 80% mean C_{max} which is about 90% to about 110% of the time to 80% mean C_{max} of an equivalent dose of an immediate release hydrocodone reference formulation, said dosage form providing a therapeutic effect for at least 12 hours.

35. A solid oral controlled-release oral dosage form comprising an analgesically effective amount of hydrocodone or a pharmaceutically acceptable salt thereof and controlled release material to render said dosage form suitable for twice-a-day administration to a human patient, said dosage form after a first administration provides a mean in-vivo absorption rate from the time of oral administration to a human patient to T_{max} of about 2 mg/hour to about 4 mg/hour and which provides a mean in-vivo absorption rate from T_{max} to about 12 hours after administration which is from about 0.08 mg/hour to about 0.4 mg/hour, said dosage form providing a therapeutic effect for at least 12 hours, based on oral administration of a dosage form containing 15 mg hydrocodone bitartrate.

36. A method of providing effective analgesia in a human patient for at least about 12 hours comprising orally administering a dosage form comprising an analgesically effective amount of hydrocodone or a pharmaceutically acceptable salt thereof, and controlled release material

to render said dosage form suitable for twice-a-day administration to a human patient, said dosage form providing after a first administration to a human patient a C_{12}/C_{max} ratio of 0.55 to 0.85 and a therapeutic effect for at least about 12 hours.

37. A process for the preparation of a solid oral controlled-release oral dosage, comprising incorporating an analgesically effective amount of hydrocodone or a pharmaceutically acceptable salt thereof, into controlled release material to make a dosage form suitable for twice-a-day administration to a human patient, wherein said dosage form after a first administration to a human patient provides a C_{12}/C_{max} ratio of 0.55 to 0.85 and a therapeutic effect for at least about 12 hours.

38. A solid oral controlled-release oral dosage form, the dosage form comprising an analgesically effective amount of hydrocodone or a pharmaceutically acceptable salt thereof, controlled release material to render said dosage form suitable for twice-a-day administration to a human patient, said dosage form after a first administration to a patient population, providing a mean C_{12}/C_{max} ratio of 0.55 to 0.85, said dosage form providing a therapeutic effect for at least about 12 hours.

39. A solid oral controlled-release oral dosage form, the dosage form comprising an analgesically effective amount of hydrocodone or a pharmaceutically acceptable salt thereof, and controlled release material to render said dosage form suitable for twice-a-day administration to a human patient, said dosage form providing an in-vitro release of at least 18% to about 42.5% by weight of the hydrocodone or salt thereof from the dosage form at one hour when measured by the USP Basket Method at 100 rpm in 700 ml of Simulated Gastric Fluid (SGF) for 55 minutes at 37°C and thereafter switching to 900 ml of Simulated Intestinal Fluid (SIF) at 37°C.

40. A solid oral controlled-release oral dosage form, the dosage form comprising an analgesically effective amount of hydrocodone or a pharmaceutically acceptable salt thereof, and controlled release material to render said dosage form suitable for twice-a-day administration to a human patient, said dosage form providing a dissolution rate in-vitro of

the hydrocodone dosage form when measured by the USP Paddle or basket method at 100rpm in 900 ml aqueous buffer at a pH of 1.2 at 37°C is from about 25 to about 65% by weight hydrocodone or salt thereof released after 2 hours, from about 45 to about 85% by weight hydrocodone or salt thereof released after 4 hours, and greater than about 60% by weight hydrocodone or salt thereof released after 8 hours.

41. A solid oral controlled-release oral dosage form, the dosage form comprising an analgesically effective amount of hydrocodone or a pharmaceutically acceptable salt thereof, and controlled release material to render said dosage form suitable for twice-a-day administration to a human patient, said dosage form providing a dissolution rate in-vitro of the hydrocodone dosage form when measured by the USP Paddle or basket method at 100rpm in 900 ml aqueous buffer at a pH of 7.5 at 37°C is from about 25 to about 65% by weight hydrocodone or salt thereof released after 2 hours, from about 45 to about 85% by weight hydrocodone or salt thereof released after 4 hours, and greater than about 60% by weight hydrocodone or salt thereof released after 8 hours.